

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1/14/05 Rec'd PCT/PTO 19 DEC 2005

Applicant: KREPINSKY et al. Examiner: Unknown  
Serial No.: 10/530,610 Group Art Unit: Unknown  
Filed: April 7, 2005 Docket: 14096.0055USWO  
Title: METHODS FOR DETECTION OF BREAST CANCER

**CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on December 12, 2005.

By:   
Name: Sarah Dannecker

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**23552**  
PATENT TRADEMARK OFFICE

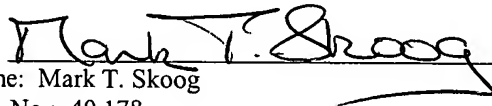
Commissioner:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Information Disclosure Statement, Form 1449, 56 Reference(s)
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C.  
P.O. Box 2903  
Minneapolis, MN 55402-0903  
612.332.5300

By:   
Name: Mark T. Skoog  
Reg. No.: 40,178  
MTS/sbd

S/N 10/530,610

PATENT

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Applicant:	KREPINSKY et al.	Examiner:	Unknown
Serial No.:	10/530,610	Group Art Unit:	Unknown
Filed:	April 7, 2005	Docket No.:	14096.0055USWO
Title:	METHODS FOR DETECTION OF BREAST CANCER		

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By: 

Name: Sarah Dannecker

**INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Commissioner:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official communication.

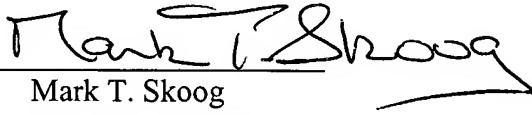
Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.



Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Dated: December 12, 2005

By:   
Mark T. Skoog  
Reg. No. 40,178

MTS/sbd

<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b> (Use several sheets if necessary)	Docket Number: 14096.0055USWO	Application Number: 10/530,610
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U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Bobo et al., "Findings From 752081 Clinical Breast Examinations Reported to a National Screening Program From 1995 Through 1998", Journal of the National Cancer Institute (2000); 92(12): 971-976
		Borg et al., "BRCA1 1675delA and 1135insA Account for One Third of Norwegian Familial Breast-Ovarian Cancer and Are Associated with Later Disease Onset than Less Frequent Mutations", Disease Markers (1999); 15: 79-84
		Bradwell et al., "Developments in Antibody Imaging", in Monoclonal antibodies for cancer detection and therapy (Baldwin RW, Ed.). Academic Press, New York 1985, pp. 65-85
		Breen et al., "Changes in the Use of Screening Mammography: Evidence from the 1987 and 1990 National Health Interview Surveys", American Journal of Public Health (1994); 84(1): 62-67
		Buckley et al., "An efficient method for labelling antibodies with <sup>111</sup> In", FEBS Lett. (1984); 166(1): 202-204
		David et al., "Protein Iodination with Solid State Lactoperoxidase", Biochemistry (1974); 13(5): 1014-1021
		Ernster et al., "Incidence of and Treatment for Ductal Carcinoma in Situ of the Breast", J. Am. Med. Assoc. (1996); 275: 913-918
		Feuer et al., "How Much of the Recent Rise in Breast Cancer Incidence Can Be Explained by Increases in Mammography Utilization?", American Journal of Epidemiology (1992); 136(12): 1423-1436
		Gotzsche et al., "Is screening for breast cancer with mammography justifiable?", The Lancet (2000); 355: 129-134

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	Greenlee et al., "Cancer Statistics, 2001", CA: A Cancer Journal for Clinicians (2001); 51: 15-36
	Greenwood et al., "The Preparation of <sup>131</sup> I-Labelled Human Growth Hormone of High Specific Radioactivity", Biochem. (1969); 113: 299-305
	Hayes, D.F., "Tumor markers for breast cancer", Anals of Oncology (1993); 4: 807-819
	Hnatowich et al., "The Preparation of DTPA-Coupled Antibodies Radiolabeled with Metallic Radionuclides: an Improved Method", Journal of Immunological Methods (1983); 65: 147-157
	Holmberg et al., "Breast cancer mortality in relation to self-reported use of breast self-examination. A cohort study of 450,000 women", Breast Cancer Research and Treatment (1997); 43: 137-140
	Hunter et al., "Preparation of Iodine-131 Labelled Human Growth Hormone of High Specific Activity", Nature (1962); 194: 495-496
	Kasten, Frederick H., "The Chemistry of Schiff's Reagent", Int. Revs. Cytol. (1960); 10: 1-100
	Katagiri et al., "High proportion of missense mutations of the BRCA1 and BRCA2 genes in Japanese breast cancer families", J. Hum. Genet. (1998); 43: 42-48
	Kelsey et al., "Epidemiology and Prevention of Breast Cancer", Annu. Rev. Public Health (1996); 17: 47-67
	Krepinsky et al., "From T-antigen to plasmalogen-derived aldehydes: The identification of a marker of colorectal cancer in human rectal mucous", Can. J. Chem. (2003); 81: 109-117
	Kuhl et al., "Healthy Premenopausal Breast Parenchyma in Dynamic Contrast-enhanced MR Imaging of the Breast: Normal Contrast Medium Enhancement and Cyclical-Phase Dependency", Radiology (1997); 203: 137-144
	Lee et al., "Association of Abnormal Nipple Aspirate Cytology and Mammographic Pattern and Density", Cancer Epidemiology, Biomarkers & Prevention (1994); 3: 33-36
	Lee et al., "The Association of Dietary Fat with Ability to Obtain Breast Fluid by Nipple Aspiration", Cancer Epidemiology, Biomarkers & Prevention (1992); 1: 277-280
	Love et al., "Breast-duct endoscopy to study stages of cancerous breast disease", The Lancet (1996); 348: 997-999
	Mandel et al., "Reducing Mortality From Colorectal Cancer by Screening for Fecal Occult Blood", New England Journal of Medicine (1993); 328(19): 1365-1371
	Marchalonis, J.J., "An Enzymic Method for the Trace Iodination of Immunoglobulins and other Proteins", Biochem. J. (1969); 113: 299-305
	Mausner et al., "Epidemiology: An Introductory Text", pp. 242-243, W.B. Saunders, St. Louis, MO. 1974.
	Merchant et al., "P Magnetic resonance phospholipid profiles of neoplastic human breast tissues", Brit. J. Cancers (1991); 63: 693-698
	Morrison et al., "Use of Lactoperoxide Catalyzed Iodination in Immunochemical Studies", Immunochemistry (1971); 8: 289-297

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		Najafi et al., "Coupling Antibody with DTPA-An Alternative to the Cyclic Anhydride", Int. J. Appl. Radiat. Isot. (1984); 35(6): 554-557
		Okazaki et al., "Relationship between Cytologic Results and the Extent of Intraductal Spread in Nonpalpable Breast Cancers with Nipple Discharge", Tumor Res. (1996); 31: 89-97
		Olsen et al., "Cochrane review on screening for breast cancer with mammography", The Lancet (2001); 358: 1340-1342
		Olsen et al., "Screening for breast cancer with mammography (Review)". 2001, Cochrane Library, issue 4, Oxford: Update Software, in press.
		Petrakis et al., "Birthplace and Yield of Nipple Aspirate Fluid in Chinese Women", Cancer Epidemiology, Biomarkers & Prevention (1998); 7: 835-839
		Petrakis, Nicholas L., "Nipple Aspirate Fluid in Epidemiologic Studies of Breast Disease", Epidemiologic Reviews (1993); 15(1): 188-195
		Petrakis, Nicholas L., "Studies on the Epidemiology and Natural History of Benign Breast Disease and Breast Cancer Using Nipple Aspirate Fluid", Cancer Epidemiology, Biomarkers & Prevention (1993); 2: 3-10
		Petrakis et al., "Association of Breast fluid coloration with age, ethnicity, and cigarette smoking", Breast Cancer Research and Treatment (1988); 11: 255-262
		Petrakis, Nicholas L., "Physiologic, biochemical, and cytologic aspects of nipple aspirate fluid", Breast Cancer Research and Treatment (1986); 8: 7-19
		Ranslow et al., "Screening for Colorectal Cancer", New England Journal of Medicine (1991); 325(1); 37-41
		Rhodes et al., " <sup>99m</sup> Tc-Labeling and Acceptance Testing of Radiolabeled Antibodies and Antibody Fragments", in Burchiel SW, Rhodes BA, Friedman BE (Eds.): Tumor imaging: The radioimmunochemical detection of cancer. Masson, New York and Paris, 1982, pp. 112-123
		Ringash, Jolie, "Preventative health care, 2001 update: screening mammography among women aged 40-40 years at average risk of breast cancer", J. Can. Med. Assoc. (2001); 164: 469-476
		Robins et al., "The structure of Schiff reagent aldehyde adducts and the mechanism of the Schiff reaction as determined by nuclear magnetic resonance spectroscopy", Can. J. Chem. (1980); 58: 339-346
		Runge et al., "Paramagnetic NMR Contrast Agents Development and Evaluation", Invest. Radiol. (1984); 19: 408-415
		Santarosa et al., "Low Incidence of BRCA1 Mutations Among Italian Families With Breast And Ovarian Cancer", Int. J. Cancer (1998); 78: 581-586
		Sartorius, Otto, "Breast fluid cells help in early cancer detection", Am. Med. Assoc. (1973); 224: 823-827
		Sauter et al., "Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk", British Journal of Cancer (1997); 76(4): 494-501
		Schaefer et al., "In Vivo Nuclear Magnetic Resonance Imaging of Myocardial Perfusion Using the Paramagnetic Contrast Agent Manganese Gluconate", JACC (1989); 14(2): 472-480

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		"Self-Reported Use of Mammography and Insurance Status Among Women Aged greater than or equal to 40 Years - United States, 1991-1992 and 1996-1997", Morbidity and Mortality Weekly Report (1998); 47: 825-830
		Shao et al., "Nipple Aspiration in Diagnosis of Breast Cancer", Seminars in Surgical Oncology (2001); 20: 175-180
		Shao et al., "The role of the breast ductal system in the diagnosis of cancer (Review)", Oncology Reports (2001); 8: 153-156
		Shreve et al., "Monoclonal Antibodies Labeled with Polymeric Paramagnetic Ion Chelates", Magnetic Resonance in Medicine (1986); 3: 336-340
		Teh et al., "The Role of Ultrasound in Breast Cancer Screening. A Consensus Statement by the European Group for Breast Cancer Screening", European Journal of Cancer (1998); 34(4): 449-450
		Wagner et al., "Denaturing High-Performance Liquid Chromatography Detects Reliably BRCA1 and BRCA2 Mutations", Genomics (1999); 62: 369-376
		Wesbey et al., "Paramagnetic Pharmaceuticals for Magnetic Resonance Imaging", Physiological Chemistry and Physics and Medical NMR (1984); 16: 145-155
		Wolf et al., "Contrast Enhancement in Biomedical NMR", Physiological Chemistry and Physics and Medical NMR (1984); 16: 93-95
		Wrensch et al., "Breast Cancer Risk Associated with Abnormal Cytology in Nipple Aspirates of Breast Fluid and Prior History of Breast Biopsy", American Journal of Epidemiology (1993); 137(8): 829-833
		Wrensch et al., "Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid", American Journal of Epidemiology (1992); 135(2): 130-141

**23552**

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